

### REMARKS

Claims 1-20 and 26 were examined. Claims 1-20 and 26 were rejected. Claim 1 is amended. Claim 2 is canceled. Claims 1, 3-20 and 26 remain in the application.

Claims 1-3, 5-9, 11, 12, 14-20 and 26 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,063,085 to Tay et al. (*Tay*) in view of U.S. Patent No. 6,539,792 to Lull et al. (*Lull*). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicant respectfully submits that a *prima facie* case of obviousness has not been established.

More particularly, none of the cited references either singly or combined provide the suggestion or motivation to modify the references. *Tay* discloses an apparatus for closing and sealing a puncture at a puncture site in a vessel located beneath the skin using radio frequency or other energy to cauterize the puncture. (col. 2, lns. 45-47) *Lull* discloses a sensor that includes a first resistor, a second resistor, a first circuit, and a second circuit wherein the first and second resistors each has a resistance that varies in response to a change in a physical property. (Abstract) According to *Lull*, the sensor can be applied in semiconductor manufacturing processes and automotive applications. (col. 17, lns. 1-5)

In contrast, independent claim 1 is directed to a needle coupled to a thermally conductive heating element, wherein the heating element is coupled to balanced circuit which measures a first differential resistance between the heating element and a variable resistor in response to a first condition and second differential resistance in response to a second condition to indicate a change of conditions related to a distance of penetration of the heating element into a tissue. Independent claim 11 is directed to a needle coupled to a thermally conductive heating element, wherein the heating element is coupled to a balanced circuit having two resistive circuit elements. According to the Application, a balanced circuit is capable of measuring heat dissipation characteristics of a tissue environment in which the heating element is disposed.

Thus, independent claims 1 and 11 contemplate an apparatus for determining injection depth and/or tissue type based on the heat dissipation characteristics of body tissue.

The nature of a problem addressed by Applicant's invention is to accurately determine injection depth of a needle in tissue other than by visual guidance means. On the other hand, the nature of the problem addressed in *Tay* is to seal puncture wounds in vessels. The nature of the problem addressed in *Lull* is to overcome a sensor's inoperability due to a circuit's inability to discern differences in flow rate of fluid due to fixed temperature coils. As such, there is no suggestion or motivation to modify the references to teach Applicant's invention. *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998) (even though the references taught every element of the claimed invention, there was no motivation to combine, rendering the rejection based on a *prima facie* case of obviousness improper). It should also be noted that neither *Tay* nor *Lull* teach a limitation of a needle having a distal portion and/or end suitable for insertion into tissue and/or capable of puncturing skin. (App., claims 1, 11) The Examiner cites *Tay* for these limitations, however, *Tay* teaches sealing wounds and not creating them, as evidenced in the specification: "[a]n apparatus for closing and sealing a vascular puncture." (col. 2, lns. 45-46) Accordingly, Applicant respectfully submits that independent claims 1 and 11 and their respective dependent claims are patentably allowable.

Claims 4 and 13 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 3,740,604 to Zenick (*Zenick*). Dependent claim 4 depends from dependent claim 2 which depends from independent claim 1. Dependent claim 13 depends from independent claim 11. Therefore, claims 4 and 13 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

Claims 10 and 18 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 5,873,835 to Hastings et al. (*Hastings*). Dependent claim 10 depends from independent claim 1. Dependent claim 18 depends from dependent claim 14 which depends from independent claim 11. Therefore, claims 10 and 18 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view

of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

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